EXHIBIT 1
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DRAFT – For HDMA Distributor Members Only
Not Intended for External Circulation

Summary by the Healthcare Distribution Management Association of the Drug Enforcement Administration's (DEA) Distributor Conference - May 10 and 11, 2016

The day and a half DEA Distributor Conference was attended by approximately 180 representatives from manufacturers, wholesale distributors and other organizations. Jim Arnold, Acting Chief, Liaison and Policy Section, DEA HQ, led the meeting. During his opening remarks, Jim emphasized that communication and outreach were a high priority under DEA's Office of Diversion Control's (ODC) new leadership. The general tone of the meeting was hospitable and DEA staff clarified their goal of seeking positive interactions.

The Conference agenda is attached and DEA stated that the slides will be posted by the end of this week at http://www.deadiversion.usdoj.gov/mtgs/index.html.

Overview

Multiple staff members from both DEA headquarters and field offices gave presentations on DEA's activities and requirements including:

- The extent, severity and impact of the drug abuse epidemic on patients and the public,
- Summary of ARCOS data on the volume of "dosage units" distributed for individual controlled substances (CS), state by state, and certain trends,
- Discussions of the Controlled Substances Act (CSA) and regulatory requirements for diversion prevention, suspicious order monitoring, reporting requirements and security,
- One session was dedicated to explaining how a DEA audit/inspection is conducted with suggestions for preparing and providing information to the inspector,
- An update of ARCOS reporting focusing on changes to the reporting systems.

Key topics of distributor interest were mentioned only in passing.

- The anticipated suspicious orders (SO) monitoring proposed rule was briefly mentioned in response to an audience question. DEA only indicated that they were "working on it" but provided no further detail.[1]
- The Ensuring Patient Access and Effective Drug Enforcement Act (HR 483) was also mentioned, but only that it had been enacted. When asked if there would be implementing regulations or guidances, DEA responded that it was under consideration.
- The Masters Case was mentioned and DEA received questions on it, but very little detail other than it involves suspicious orders and due diligence was discussed.

Suspicious order reporting received considerable attention, mostly due to a number of audience questions. In particular, an attendee asked Scott Davis, Diversion investigator from DEA's Philadelphia Field Division, for clarification of a specific direction given to the questioner by their local DEA field

[1] HDMA has learned that at a recent DEA conference for pharmacists, DEA indicated that they had changed their plans and were going to issue a "guidance" rather than a regulation. DEA did not mention this change at the Distributor Conference, and only referred to the forthcoming document as a regulation.

agent. Apparently, the field agent had stated that if a computer algorithm noted that a specific particular order should be looked at as potentially suspicious (*i.e.*, gave a "red flag" or indicated it was an "order of interest") the company should report the order based on the red flag. Scott stated that he thought it should be reported.

Others in the audience further questioned Scott's view, explaining that they didn't report such red flags, and that as a second step, they also had an employee review the order (*e.g.,* contact the customer) before determining whether an order was "suspicious". Scott backed off and said that the DEA Counsel's office would speak the next day and that they should provide the response.

Similar questions about reporting "orders of interest" came up again. The next day's speaker from the DEA Chief Counsel's office (Dedra Curteman) stated that if a company had a Memoranda of Agreement (MOA) with DEA which specified they must report "Orders of Interest" they should do so. Otherwise, the regulations did not require reporting red flags. The requirement was to report suspicious orders.

Information of interest

Most of the discussions repeated information and legal requirement that have been previously explained in other DEA (and HDMA) meetings/conferences. Below are a few items that may be of interest:

- HDMA suggests you review the slides when posted. Those towards the end of Jim Arnold's presentations where he shows current and upcoming activities and the listings of inspection findings/violations may be the most interesting. [Note: Jim went through these very quickly since he was running out of time. He did not provide much additional explanations of them.]
- Scott Davis recommended that registrants create a "DEA Audit Book" with information that a DEA auditor is likely to request. This way, the registrant could rapidly respond to an auditor's requests for key information such as:
  - A description of the company (size, products, suppliers, customers, services, etc.)
  - Names and responsibilities of leadership/management and the Board of Directors
  - SOPs for how the company places orders, receives orders, secures products and screens employees
  - Further suggestions of what the SOPs might cover included: who has Power of Attorney; who receives an order; how they verify the order; name, address, SSN of personnel who have access to cage and vault
- Scott Davis also noted that during inspections, auditors were looking for "balance." That is, no discrepancies in the records, for example, between what the firm ordered and what they received, or what a customer ordered and what the firm shipped.
- ARCOS –
  - DEA has created a mechanism that allows a wholesale distributor to upload the product label (with an NDC). By doing this, wholesalers may be able to avoid the error code E-76 when they submit ARCOS information, which occurs because the manufacturer hasn't submitted the NDC used to compare to the wholesaler's ARCOS NDC.
  - Many other ARCOS errors are related to the NDC formatting, which is different from the format FDA issues.
  - DEA will not allow exceptions to the ARCOS reporting deadlines. The only way an exception would be granted is if the Dep. Assistant Administrator approves one.
  - DEA's website now shows a data summary called: "Retail Summary Reports."

Qs and As of Interest

There were two Q and A sessions, one at the end of each day. The following is not all inclusive, but rather a summary of those that may be of particular interest.

Q. What should a company do in the following circumstance? The company has several warehouses located in different DEA field locations [hypothetically, five warehouses total] and one DEA field agent stated that an SOP used in the warehouse in his area is inadequate. The exact same SOP is used in the other four warehouses but the DEA field offices in those areas have not found them inadequate.
A. Jim Arnold's initial answer was that the registrant should look at the problems identified by the field agent and correct them in all the warehouses, including the other four. But with audience further questioning, he backed off and said that the registrant should contact him for verification of the requirement.

Q. One state (GA) won't allow wholesalers to view pharmacy information that DEA suggests they obtain/review. What should the wholesaler do?
A. DEA needs to address this on our end. In the meantime, get what you can. e.g., use questionnaires, interviews, on site visits, etc.

Q. What is the status of the scheduling action on Propofol?
A. We're looking at it. It's moving internally.

Q. Is "Trinity"[2] ever legitimately prescribed?
A. Theoretically, it's possible, but we've never seen such an instance.

Q. Does DEA ever recommend that prescribers avoid prescribing the "Trinity"?
A. DEA's expertise does not include prescribing practices. Thus, we would not recommend against it.

Q. The list of violations Jim Arnold presented included one about the "failure to document transfers between registrants" -- can you elaborate on when and what these failures were?
A. If there is a transfer between any two locations where each holds a DEA registration number, even when owned by the same company, a transfer between those two locations should be documented. We find that sometimes the registrant does not document such transfers.

Q. Will DEA share more ARCOS data with the states?
A. We sometimes share ARCOS information on a case-by-case basis. But we do not have a general plan to share ARCOS data across the board.

Q. If someone reports a "suspicious customer" what does DEA do with that report?
A. DEA will look at any information that comes in and it may become a larger investigation. We won't tell you what we'll do. We also won't tell the firm that is the subject of the report that their supplier told DEA about them. Our primary concern, however, is the suspicious order since that's what is required to be reported.

[2] "Trinity" sometimes called "Cocktail" -- when an individual takes Hydrocodone, Carisoprodol/Soma and Alprazolam/Xanax in combination.

Q. [From a manufacturer] I mostly deal with the largest wholesale distributors. However, I have difficulties with determining what they should do regarding their customer due diligence responsibilities. Their customers are so far down the supply chain that it's almost impossible [for my firm] to find information "that far down." I may not have chargeback information to help out, either.
A. Use the chargeback information if you have it. Otherwise do your best.

Q. Several audience members (including non-wholesale distributor attendees) asked questions about situations in which companies distributing CS were uncertain about whether an order should be regarded as suspicious. Usually they gave examples of situations they had encountered. These attendees requested DEA's guidance on whether such circumstances required further evaluation and how to do so.
A. DEA essentially responded to these questions with such answers as: "ask the customer more follow-up questions, such as why they need more of the product," "I can't respond further without knowing the answers to your additional investigation questions" or "you have to use your own judgment" etc. The Chief Counsel's office emphasized the need for an "expedited process" *i.e.,* urged that registrants work quickly to resolve the "red flag" if one is found. DEA staff also emphasized that it was important for the registrant to follow their own SOPs.

Q. Does DEA talk to the registrant before they issue an ISO?
A. No.

Q. What does DEA require for employee screening?
A. We have not issued screening "requirements" -- only suggestions. Those are in the CFR. Registrants should use their own good judgment.

Closing
The Conference closed shortly after noon on the second day. DEA thanked the audience for their participation and emphasized that they are open to additional questions after the conference closed.